Comments and suggestions may be submitted at any time for Agency consideration to Charles Gunzburg, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next

http://www.fda.gov/cdrh/dmqrp/6400.html
The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations, which replaced the interim regulations (58 FR 67558 and 58 FR 67565) which, under MQSA, previously regulated accreditation of mammography facilities.

The FDA is planning a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing written materials to the public. The currently available written documents include the
MQSA requires each facility conducting mammography in the United States (except those of the

- meet quality standards for personnel, equipment, maximum allowable radiation dose, quality
  assurance, medical audit and outcome analysis, medical recordkeeping and reporting
- be accredited by a Food and Drug Administration (FDA)-approved accreditation body (AB)
  (currently, the American College of Radiology [ACR] and the States of Iowa, California, and
- be certified to perform mammography by the FDA, the States of Illinois or Iowa, or another
  State certification body approved by the FDA (each certified facility must prominently
certificate where it can be viewed by mammography patients); and

- having an annual survey performed by a qualified medical physicist,
- undergoing an annual inspection conducted by an MQSA inspector,
- paying an inspection fee (and, where applicable, re-inspection fees), and
- correcting any deficiencies found during these processes.

NOTE: The Health Care Financing Administration accepts MQSA certification as evidence of compliance with mammography quality standards. Only facilities with a current MQSA certificate will be eligible to receive Medicare/Medicaid payment for screening and diagnostic mammography.

During each inspection, MQSA inspectors check for the facility's compliance with MQSA quality standards, and all deficiencies found must be corrected by the facility. Most of the October 28, 1997, regulations will become effective on April 28, 1999, with the remainder becoming effective on October 28, 1999. Inspections will not cover any new regulation before its effective date. Until a regulation becomes effective, it will be covered under the December 21, 1993, MQSA regulations as specified in the previous issues of this document.

To reduce the inspection time, the scope of the standard inspection questions has been limited to items that FDA believes have the most direct bearing on facility performance and mammographic quality. However, the facility remains responsible for meeting all requirements of the regulations, not only those specifically listed in the inspection procedures. Concurrent with the MQSA inspection, States may inspect for some items that are required by their laws and regulations. However, these items will not affect the facility's compliance with MQSA or the associated MQSA inspection fee.

Under MQSA, each facility location will be inspected at least annually for the following:
- Equipment performance
- Quality Assurance (QA) records
- Quality Control (QC) records and tests
- Technologist tests
- Medical physicist's annual survey report
- Personnel qualification records
- Medical records (mammography reports and films)
- Medical audit and outcome analysis records

Mobile mammography facilities may provide services at multiple locations under the same certificate. Each location is recognized by FDA as a part of that facility and is subject to inspection. Each such site may be inspected. The scope of inspections at sites where mobile mammography activities are conducted will vary depending on the type of mammography services provided at each location, with or without the mobile x-ray system being at that location. In general, all sites are subject to inspection for all requirements related to MQSA services provided at that location. The facility representative may request details regarding tests and record requirements for scheduled inspections of such sites from the inspector during the prior notification and scheduling process.
FDA will inspect each x-ray system used by the facility for regulated mammography activities. This inspection includes equipment being leased by, loaned to, or evaluated for purchase, as well as equipment owned by the facility. For several of these tests, the inspector will use the facility's film and cassettes to ensure the applicability of the results to the facility. The inspector will also require assistance from facility personnel in setting up technique factors normally used by the facility for an average breast examination and operating the equipment, as well as any other preparatory work needed.

Determination that the equipment has been designed specifically for mammography.

http://www.fda.gov/cdrh/dmqrp/6400.html
To meet item number 2, the facility must have at least one of each of the listed items for each mammography x-ray unit in the facility. There is no requirement that image receptor sizes other than the 18 X 24 and 24 X 30 be available for each unit in the facility. However, if a facility uses additional (not required by the regulations) image receptor sizes, the facility must have at least one moving grid and compression paddle for each such additional size (it is not necessary to have these for each x-ray

Facilities should maintain specific records regarding each regulated mammography system. These

- X-ray unit accreditation status
- Equipment evaluation for new/repaired equipment
- Annual survey reports (both the most recent and the previous one)
- Evidence of post-move performance testing for mobile units
- QC test records

http://www.fda.gov/cdrh/dmqrp/6400.html
Evidence of any corrective actions taken

The facility should have documentation showing that each x-ray unit has been accredited by the accreditation body. For a new unit, the facility must show that it has passed an equipment evaluation or medical physicist’s survey prior to use on patients and that the application for accreditation of the unit under preparation will be adequate to establish compliance.

There are three cases where a unit in use may not need to be accredited:

- The unit is a “loaner,” while repairs to the facility’s unit are taking place, or awaiting delivery of a replacement unit (limited to 30 days without extenuating documentation from the service or dealer organization showing reasons for delay in replacement or repair);
- The unit is installed in the facility for evaluation before purchasing (limited to 90 days maximum);
- The unit is an experimental one, installed and used under an FDA investigative device exemption.

Note: Under both 1. and 2. the unit still must have passed an equipment evaluation before use on patients. The above time frames and allowances are permitted under MQSA. Under State or local regulations and accreditation body policies, all such use may require registration or accreditation. Be sure to verify the requirements with these sources.

The QA program includes the designation of appropriate, qualified personnel to implement and oversee the QA process. These personnel must include a lead interpreting physician, medical physicist, and quality control technologist. The inspector will check to establish that qualified personnel have been designated for each of these duties and that the facility has established a QA program, as required by the regulations, to "ensure the safety, reliability, clarity, and accuracy of the mammography services.

Evaluation of the QA program includes the review of QA procedures and records for all of the requirements outlined in 21 CFR 900.12(d) and (e). Facilities are required to retain the QC records for each test specified by the regulations until the next annual MQSA inspection has established that the facility is in compliance with the QA requirements, or until the test has been performed two additional times at the required frequency, whichever is longer. Although these records must be maintained and available for review, not all records will always be evaluated during each inspection. However, the

- Daily Processor Quality Control
  - Including actual sensitometric film strips for the previous 30 days of mammographic film processing and charting of the strips for the period specified above

- Weekly Phantom Images
  - Including phantom images for the previous 90 days, and records covering the remainder

http://www.fda.gov/cdrh/dmqrp/6400.html
more frequently than the annual tests in __________ and will normally fall under the responsibility of

http://www.fda.gov/cdrh/dmqrp/6400.html
the quality control technologist. The annual tests and their regulatory requirements are summarized in [125x714]. Although these tests may be conducted at any time, they also must be conducted by a MQSA-qualified medical physicist (or someone in training under his or her direct supervision) as part of the annual survey. The results of the annual tests and any recommendations for corrective actions must be stated in the medical physicist's survey report.

The facility must have available for the inspector the two most recent annual physicist survey reports. The reports must document the physicist's tests, the results, the evaluation of the technologist's QC testing, and include recommendations of any corrective actions resulting from the tests or review. The facility should also have evidence of its actions concerning each recommendation.

When a new or an existing mammography facility obtains new radiographic equipment or processors, it must have the equipment evaluated by a qualified medical physicist before such equipment is placed in service. In this context, "new" means new to the facility and may be previously used equipment. In addition, such "equipment evaluations" must be performed whenever such equipment is disassembled and then reassembled, either at the same or a new location, or whenever a major component is changed or repaired. The inspector will verify that appropriate records are available to document compliance. There are no specific requirements for the records associated with this evaluation. The medical physicist should provide the facility with sufficient documentation to clarify the testing performed and the results of the testing. All problems must be corrected before the new or changed equipment is put into service for examinations or film processing.

The facility is required to maintain records documenting qualifications of all personnel who have performed or are performing the duties of interpreting physician, radiological technologist, or medical physicist for the facility. This requirement covers records for individuals who provide or have provided temporary and/or contract services for the facility, including personnel who may provide services offsite. Records must cover the status of the permanent and temporary staff at the start of employment, during the period of employment, and at termination. Once an employee leaves, the facility is not expected to continue tracking their status. If personnel leave, the facility is expected to maintain their records until the next annual MQSA inspection has been completed and FDA has determined that the facility complies with all MQSA personnel requirements.

Facilities should be aware that their State(s) might have more stringent recordkeeping requirements. Check with your State(s) before making any final decisions regarding the disposition of any records.
Have a minimum of 60 hours of documented category I medical education in mammography (including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography). At least 15 of the required 60 hours must have been acquired within the 3 years immediately before the physician's initial qualification date. These 60 hours may be included in the 3 months of training specified in 2.b above. Hours received in residency training are considered equivalent to category I.

Have interpreted or multi-read, under direct supervision of a qualified interpreting physician, at least 240 mammographic examinations within the 6-month period immediately before the date that the physician qualifies as an interpreting physician (or in any 6-month period during the last 2 years of a diagnostic radiology residency for physicians who become appropriately board certified at the first allowable time, as defined by the board).

Before an interpreting physician may begin independently interpreting mammograms produced by any mammographic modality in which the interpreting physician was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the physician must have at least 8 hours of training in that mammographic modality.
Have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, the last day of the calendar quarter preceding the inspection. The starting date for meeting the continuing experience requirement is the later of October 1, 1994, or the individual's starting date. Failure to meet the continuing experience requirement will not be considered a noncompliance until 24 months after the individual's starting date.

Have taught or completed at least 15 category I continuing medical education (CME) credits in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, the last day of the calendar quarter preceding the inspection. Any date in between the two. CME credits earned through teaching a course can be counted only once toward meeting the 15 credits required in any 36-month period. Such training shall include at least 6 credits of category I CME in each mammographic modality used. The starting date for meeting the continuing experience requirement is the later of October 1, 1994, or the individual's starting date. Failure to meet the continuing education requirement will not be considered a noncompliance until 36 months after the individual's starting date.

FDA permits multi-reading/interpreting of mammograms and summing of readings/interpretations from different facilities in calculating the total mammographic examinations for items 4 and 6 above. Multi-reading is defined as two or more physicians, at least one of whom is a fully qualified interpreting physician, interpreting the same mammogram. Multi-reading includes reading comparison mammograms not previously read by the physician.

So that facilities are aware of potential problems, FDA recommends that facilities update education and certification requirements of item 1, any applicable new modality training, and the continuing experience and education requirements of items 4 and 5. Have a general/full license to perform radiographic procedures issued by a State.

http://www.fda.gov/cdrh/dmqrp/6400.html
b. Board Certification:

- The American Registry of Radiologic Technologists (ARRT)
- The American Registry of Clinical Radiography Technologists (ARCRT)

Initial Training in Mammography:

Have at least 40 contact hours of mammography training, including breast anatomy, physiology, positioning, compression, quality assurance/quality control techniques, imaging of patients with breast implants. Time spent performing supervised examinations may be included in the 40-hour total. As guidance, however, no more than 12.5 hours of the required 40 should come before a radiologic technologist may independently perform mammographic examinations using any mammographic modality in which the radiologic technologist was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the radiologic technologist must have at least 8 hours of training in the

Have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection, the last day of the calendar quarter preceding the inspection, __

The starting date for meeting this requirement is April 28, 1999, or the date on which the individual initially qualifies to work independently, whichever is later. Failure to meet the technologist's continuing experience requirement will not be considered a noncompliance until the later of July 1, 2001, or 24 months after the technologist's starting date.

Have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual the last day of the calendar quarter preceding the inspection, __

between the two. At least 6 of these CEUs must be in each of the mammographic modalities used by the technologist. CEUs earned through teaching a course can be counted only once towards meeting the units required in any 36-month period.

The starting date for meeting the continuing education requirements is the later of October 1, 1994, or the technologist's starting date. Failure to meet the continuing education requirements will not be considered a noncompliance until 36 months after the technologist's starting date.

As with the physicians, FDA recommends that the facilities update the education and experience

http://www.fda.gov/cdrh/dmqrp/6400.html
The qualifications for the medical physicist are relatively complicated. As an aid to understanding them, we have separated the medical physicist section into three parts.

The requirements for those physicists who are qualifying through the "master's degree or higher" route must demonstrate:

- Be licensed or approved by a State to perform mammography.
- Have at least a master's degree or higher in a physical science with at least 20 semester hours (30 quarter hours) of graduate or undergraduate physics.
- Have at least 20 contact hours of mammography facility survey.
- Have the experience of conducting surveys of at least 1...
Certain medical physicists may have qualified under the interim regulations before April 28, 1999, through the State approval or licensing mechanism or through the professional certification route without having the appropriate degree to meet the final regulations as described above. Such medical physicists may qualify under the "route. Such individuals must demonstrate that, by April 28, 1999, they have achieved compliance with the following:

a. Licensure or approval:
   - Be licensed or approved by a State to perform mammography

b. Board Certification:
   - Be certified in diagnostic medical physics by one of the following:
     - The American Board of Radiology (ABR)
     - The American Board of Medical Physics (ABMP)

Education, training, and experience:

- Have a bachelor's degree in a physical science with at least 10 semester hours (15 quarter hours) of graduate or undergraduate physics. (This would include individuals having advanced degrees in non-physical science fields.)

- Have at least 40 contact hours of mammography facility survey training. This training must have occurred after fulfilling the degree requirement in 2.a.

- Have the experience of conducting surveys of at least 1 at least 20 mammography units. This initial experience must have occurred after fulfilling the degree requirement in 2.a.

All medical physicists must meet the following requirements;

Before a physicist may begin independently performing surveys or equipment evaluations on any mammographic modalities in which the physicist was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the physicist must have at least 8 hours of training in the modality.

The physicist must have conducted a minimum of two a total of six mammography unit surveys (evaluations which cover all of the equipment survey items) during the 24 months immediately preceding the date of the facility's annual MQSA inspection, the calendar quarter preceding the inspection,

The starting date for this requirement is April 28, 1999 or the date on which the physicist

http://www.fda.gov/cdrh/dmqrp/6400.html
The starting date for this requirement is October 1, 1994, or the date on which the physicist initially qualifies to work independently, whichever is later. Failure to meet the physicist's continuing education requirement will not be considered a noncompliance until 36 months after the physicist's starting date.

Have taught or completed at least 15 continuing education units in medical physics or mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding any date in between the two. The continuing education must include training appropriate to each mammographic modality evaluated by the medical physicist. CEUs earned through teaching a course can be counted only once toward meeting the 15 units required in any 36-month period.

NOTE: For meeting the requirements in items A.2.b., A.2.c., B.2.b., B.2.c., and C.2., FDA allows multiple testing of the same mammography unit. However, no more than one survey of a specific facility within a 10-month period can be counted toward the total requirement, and tests of the same unit cannot be counted more than once in any consecutive 60-day period. It is important enough to repeat that, for the alternative initial qualifications route, the training and experience in items B.2.b. and B.2.c. must have been obtained after the qualifying degree requirements are satisfied and before.

Specific information on acceptable documentation for the physicist's qualifications is listed in Under the interim regulations, personnel were allowed to attest to certain training, education, or experience earned before October 1, 1994. FDA does not intend to accept attestation for training, education, or experience obtained after October 1, 1994, by personnel qualifying after April 28, 1999. However, a limited form of attestation for CME/CEUs earned after October 1, 1994, will be accepted if a continuing education provider does not specifically document the number of hours earned in mammography. Such attestation must include documentation showing both the total number of CME/CEUs earned in the program and the total number of CME/CEUs specific to mammography that were available. If the meeting or other educational opportunity is limited to mammography, then only documentation from the provider of the number of CME/CEUs earned is needed. Attestation will not be accepted for establishing any qualifying degree requirements for medical physicists, including the required number of hours in physics, even if these conditions were satisfied prior to October 1, 1994. All attestations must be in the proper format. (An attestation form is included as...
Medical records must contain certain required types of information. To ensure that both the mammographic images and reports are being retained as required, and to verify they contain the information outlined below, the inspector will randomly select records for review. In general, the inspector will request reports from those examinations performed since the last MQSA inspection, or since the facility's certification, whichever is the most recent. However, inspectors may examine records from other time frames. The inspector will not attempt to assess the correctness of these reports, but will determine that the records are being generated, properly maintained, and identify the interpreting physician who originally interpreted the mammograms. For those records created on or after April 28, 1999, the inspector will also verify that appears in each: "Negative," "Benign," "Probably Benign," "Suspicious," "Highly suggestive of malignancy," or "Incomplete: Need additional imaging evaluation."

The facility is required to communicate the results, within 30 days of the examination, to the referring health care provider and to the patient (lay summary). In the case of self-referred patients, if a health care provider (or a responsible designee) is not named or is unavailable, then the report must be provided to the patient. Communications to the patient, if there is no health care provider, must include 1) the complete report of findings referenced above and 2) the summary written in lay terms that is required for all patients. When the assessment is "Suspicious" or "Highly suggestive of malignancy," the facility is required to communicate the results, as soon as possible, to the referring health care provider and to the patient (lay summary) and depending on health care provider availability, may need to send the complete report to the patient. Facility personnel should be prepared to explain the facility's procedure for communicating results to referring physicians and to patients and their mechanism for providing quick response for cases requiring such action.

FDA's concern is not the details of the communication system but rather:

- that one has been established by the facility,
- that it is in place, and
- that it meets the requirements of the regulations.

The inspector will verify that the communication system meets these criteria and that lay summaries are available. If patient records are stored in an electronic format, the inspector will ask the facility to assist in the selection and retrieval of the records to be inspected.

Each facility must establish and maintain a system to track positive mammographic findings and to correlate such findings with the biopsy results the facility obtains. At a minimum, the system must track "positive mammographic findings," which refers to mammograms interpreted as "Suspicious" or "Highly suggestive of malignancy." Facilities must also include in their audit any patients that they become aware of who were subsequently found to have cancer that was not detected through their certified, or 12 months after April 28, 1999, whichever date is later. The first and all subsequent audit within 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is later. The first and all subsequent audit within 12 months and be reviewed by a "reviewing interpreting physician" appointed by the facility. The "reviewing interpreting physician" has multiple responsibilities listed in 900.12(f)(3) that must be covered in the facility's audit program.

The inspector will examine the audit system for the inclusion of the above items, ascertain how biopsy

http://www.fda.gov/cdrh/dmqrp/6400.html
If major deficiencies are found, the facility will receive a letter, addressed to the facility's "Responsible Person," concerning these issues. The facility's "Responsible Person" is a person the facility has identified as having the authority to make vital operational and financial decisions concerning corrective actions that are required to bring the facility into compliance. All deficiencies should be corrected as soon as possible. Depending on the level of the severity of the problems, specific regulatory mandated time frames will be included in the letter. For violations related to the quality control (QC) tests described in paragraph 900.12(e)(8)(ii)(B), the facility must complete repairs within

The facility is required [21 CFR 900.12(e)(8)(ii)(A)] to correct problems found with the following areas of the QC program "before any further examinations are performed or any films are processed using the component of the mammography system

- Daily QC tests - 900.12(e)(1),
  - base plus fog
  - mid-density
  - density difference

- Weekly QC tests - 900.12(e)(2)
useful items, including current information about the mammography program. If you have questions on how to prepare for inspections, call FDA’s Mammography Program at (800) 838-7715, or FAX your

**Regarding Requirements of the Mammography Quality Standards Act**

Attestation must include as much of the following information as possible:

Name of the institution/facility where the applicable training or mammography reading/interpreting, or other activity, took place; name of the course(s) or training (where applicable); the attendance,

http://www.fda.gov/cdrh/dmqrp/6400.html
<table>
<thead>
<tr>
<th>Test &amp; Frequency</th>
<th>Requirements for Acceptable Operation</th>
<th>Guidance for Acceptable Documentation Retention*</th>
<th>Timing of Required Corrective Action **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processor QC- Daily</td>
<td>Established operating level for B+F, + up to</td>
<td>QC records (&amp;charts) for the last 12 months or since the last</td>
<td>Before any further clinical films are processed.</td>
</tr>
</tbody>
</table>

http://www.fda.gov/cdrh/dmqrp/6400.html
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Operating Level</th>
<th>QC Records Details</th>
<th>Time Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phantom QC - Weekly</td>
<td>± 0.15 OD</td>
<td>QC charts &amp; records for the last 12 months or since the last inspection, whichever is longer. Phantom images for the last 12 weeks.</td>
<td>Within 30 days of the date for the next inspection.</td>
</tr>
<tr>
<td>Fixer retention in film</td>
<td>± 0.05</td>
<td>QC Records since the last inspection or for the past three tests, whichever is longer.</td>
<td>Before any further clinical films are processed.</td>
</tr>
<tr>
<td>Compression Device</td>
<td>≥ 111 newtons (25 pounds).</td>
<td>QC records since last inspection or for the past three tests, whichever is longer.</td>
<td>Before any further examinations are performed using the compression device.</td>
</tr>
</tbody>
</table>

Guidance regarding the length of time for which the facility is required to keep QC records was given
earlier under 900.12(d)(2).
** Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.

### Annual Quality Control Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Final Regulation</th>
<th>Regulatory Action</th>
<th>corrective action*</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEC</td>
<td></td>
<td>Corrective action</td>
<td>Within 30 days of the date of the test.</td>
</tr>
<tr>
<td>kVp</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Focal spot</td>
<td>900.12(e)(5)(iii)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HVL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air Kerma and AEC reproducibility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td></td>
<td>Exceeds 3.0 mGy (0.3 rad) per exposure.</td>
<td></td>
</tr>
<tr>
<td>X-ray field / light field / compression device alignment</td>
<td>900.12(e)(5)(vii)</td>
<td>Paddle visible on</td>
<td>Within 30 days of the date of the test.</td>
</tr>
<tr>
<td>Screen speed uniformity</td>
<td>900.12(e)(5)(viii)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>System artifacts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Requirement</td>
<td>Obtained Prior to</td>
<td>Obtained 10/1/94-</td>
<td>Obtained after 4/28/99</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Radiation output</td>
<td>900.12(e)(5)(x)</td>
<td>Less than 4.5 mGy/sec (513 mR/sec).</td>
<td>&quot;</td>
</tr>
<tr>
<td>Automatic decompression control</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any applicable modality tests</td>
<td></td>
<td></td>
<td>Before any further examinations are</td>
</tr>
</tbody>
</table>

* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable

### Acceptable Documents For Interpreting Physicians

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Obtained Prior to</th>
<th>Obtained 10/1/94-</th>
<th>Obtained after 4/28/99</th>
</tr>
</thead>
<tbody>
<tr>
<td>State License</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Board Certification (ABR, AOBR, or RCPSC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formal Training (2 months-interim regs)</td>
<td>1. Letters or other documents from US or Canadian residency</td>
<td>1. Letters or other documents from US or Canadian residency</td>
<td>1. Letters or other documents from US or Canadian residency</td>
</tr>
<tr>
<td>(3 months-final regs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td><strong>Initial Medical Education</strong>&lt;br&gt;(40 hours-interim regs)&lt;br&gt;(60 hours/15 in last 3 years-final regs)</td>
<td>2. Documentation of formal mammography</td>
<td>3. Category I CME</td>
<td></td>
</tr>
<tr>
<td><strong>Initial Experience</strong>&lt;br&gt;(any 6 month period-interim regs)&lt;br&gt;(last 6 months vs 6 months in last 2 years of residency-final regs)</td>
<td>1. Attestation</td>
<td>2. Letter from residency or training mammography facility - done under direct</td>
<td></td>
</tr>
<tr>
<td>3. CME certificates</td>
<td>3. Letter or other document confirming in-house or formal</td>
<td>3. Letter or other document confirming in-house or formal training (category I)</td>
<td></td>
</tr>
<tr>
<td>4. Letter or other document confirming in-house or formal</td>
<td>4. Letters, certificates, or other documents from manufacturers' or other formal training</td>
<td>4. Letters, certificates, or other documents from manufacturers' or other formal training</td>
<td></td>
</tr>
</tbody>
</table>

http://www.fda.gov/cdrh/dmqr/6400.html
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Documentation Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing Experience (960/24 months)</td>
<td>N/A</td>
</tr>
<tr>
<td>Full Name of Facility</td>
<td>1. Letter, table, facility logs, or other documentation from residency or training program or mammography facility</td>
</tr>
<tr>
<td>Full Name of Facility</td>
<td></td>
</tr>
<tr>
<td>Continuing Education (15 CME/36 months-interim regs) (15 category I CME/36 months-final regs)</td>
<td></td>
</tr>
<tr>
<td>Continuing Mammographic Modality Specific Education-final regs</td>
<td></td>
</tr>
<tr>
<td>Requalification-Experience-done under direct supervision</td>
<td>1. Letter, table, facility logs, or other documentation from residency or training program or mammography facility</td>
</tr>
<tr>
<td>Requalification-</td>
<td>1. CME certificates</td>
</tr>
</tbody>
</table>
### Attachment 5

**Acceptable Documents For Radiologic Technologists**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Obtained Prior to</th>
<th>Obtained 10/1/94-</th>
<th>Obtained after 4/28/99</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State Licensure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Board Certification</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ARRT or ARCRT)</td>
<td>1. Original/copy of current certificate</td>
<td>1. Original/copy of current certificate</td>
<td>1. Original/copy of current certificate</td>
</tr>
<tr>
<td></td>
<td>2. Confirming letter from certifying board</td>
<td>2. Confirming letter from certifying board</td>
<td>2. Confirming letter from certifying board</td>
</tr>
<tr>
<td></td>
<td>3. Pocket card/copy of</td>
<td>3. Pocket card/copy of</td>
<td>3. Pocket card/copy of</td>
</tr>
<tr>
<td><strong>Initial Training</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(~40 hours-interim regs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. CEU certificates</td>
<td>2. CEU certificates</td>
<td>2. CEU certificates</td>
</tr>
<tr>
<td></td>
<td>4. Letter or other document confirming in-house or formal</td>
<td>3. Letter or other document confirming in-house or formal training</td>
<td>3. Letter or other document confirming in-house or formal training</td>
</tr>
<tr>
<td><strong>Initial</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1. Mammography modality</td>
</tr>
</tbody>
</table>

http://www.fda.gov/cdrh/dmqrp/6400.html
<table>
<thead>
<tr>
<th>Mammography Modality Specific Training (8 hours-final regs)</th>
<th>Mammography modality specific CEU certificates</th>
<th>Mammography modality specific CEU certificates</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Mammography modality specific CEU certificates</td>
<td>2. CEU certificates plus agenda, course outline, or syllabus</td>
<td>2. CEU certificates plus agenda, course outline, or syllabus</td>
</tr>
<tr>
<td>3. CEU certificates plus agenda, course outline, or syllabus</td>
<td>3. Confirming letters from CEU granting organizations</td>
<td>3. Confirming letters from CEU granting organizations</td>
</tr>
<tr>
<td>4. Confirming letters from CEU granting organizations</td>
<td>4. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
<td>4. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
</tr>
<tr>
<td>5. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Continuing Experience (200/24 months-final regs)</th>
<th>Letter, table, facility documentation from training program or mammography facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Letter, table, facility documentation from training program or mammography facility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Continuing Education (15 CME/36 months)</th>
<th>CEU certificates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CEU certificates</td>
<td></td>
</tr>
<tr>
<td>2. Confirming letters from</td>
<td></td>
</tr>
<tr>
<td>3. Formal training</td>
<td></td>
</tr>
<tr>
<td>4. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Continuing Mammographic Modality Specific Education-final regs</th>
<th>Mammography Modality Specific CEU certificates</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mammography Modality Specific CEU certificates</td>
<td></td>
</tr>
<tr>
<td>2. CEU certificates (plus agenda, course outline, or syllabus)</td>
<td></td>
</tr>
<tr>
<td>3. Confirming letters from CEU granting</td>
<td></td>
</tr>
<tr>
<td>3. Confirming letters from</td>
<td></td>
</tr>
</tbody>
</table>

http://www.fda.gov/cdrh/dmqrp/6400.html
### Acceptable Documents For Medical Physicists

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Obtained Prior to 10/1/94</th>
<th>Obtained after 4/28/99</th>
</tr>
</thead>
<tbody>
<tr>
<td>State Licensure or Approval</td>
<td>1. State license or approval/copy with</td>
<td>1. State license or approval/copy with</td>
</tr>
<tr>
<td></td>
<td>2. Confirming letter from State licensing board</td>
<td>2. Confirming letter from State licensing board</td>
</tr>
</tbody>
</table>

http://www.fda.gov/cdrh/dmqrp/6400.html
<table>
<thead>
<tr>
<th>Board Certification (ABR or ABMP)</th>
<th>1. Original/copy of certificate</th>
<th>1. Original/copy of certificate</th>
<th>1. Original/copy of certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Confirming letter from certifying board</td>
<td>2. Confirming letter from certifying board</td>
<td>2. Confirming letter from certifying board</td>
</tr>
<tr>
<td>Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway - alternative)</td>
<td>1. Original/copy of</td>
<td>1. Original/copy of</td>
<td>1. Original/copy of</td>
</tr>
<tr>
<td></td>
<td>2. Confirming letter from college or university</td>
<td>2. Confirming letter from college or university</td>
<td>2. Confirming letter from college or university</td>
</tr>
<tr>
<td>Initial physics education-final regs (20 semester hours) (10 semester hours -alternative)</td>
<td>1. College or university</td>
<td>1. College or university</td>
<td>1. College or university</td>
</tr>
<tr>
<td></td>
<td>2. Confirming letter from college or university</td>
<td>2. Confirming letter from college or university</td>
<td>2. Confirming letter from college or university</td>
</tr>
<tr>
<td>Survey Training-final regs (20 contact hours) (40 contact hours -alternative)</td>
<td>1. College or university</td>
<td>1. College or university</td>
<td>1. College or university</td>
</tr>
<tr>
<td></td>
<td>2. Confirming letter from college or university</td>
<td>2. Confirming letter from college or university</td>
<td>2. Confirming letter from college or university</td>
</tr>
<tr>
<td></td>
<td>3. Letter or other document confirming in-house or formal training</td>
<td>3. Letter or other document confirming in-house or formal training</td>
<td>3. Letter or other document confirming in-house or formal training</td>
</tr>
<tr>
<td></td>
<td>4. Training gained performing surveys</td>
<td>4. Training gained performing surveys</td>
<td>4. Training gained performing supervised</td>
</tr>
<tr>
<td>Initial Experience-</td>
<td>1. Copy or coversheet of</td>
<td>1. Copy or coversheet of</td>
<td>1. Copy or coversheet of</td>
</tr>
</tbody>
</table>

http://www.fda.gov/cdrh/dmqrp/6400.html
<table>
<thead>
<tr>
<th>Training Type</th>
<th>Required Documentation</th>
</tr>
</thead>
</table>
| **Initial Mammography**<br>Modality Specific training (8 hours-final regs) | 1. Copy or coversheet of survey<br>2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done<br>3. Letter from facility or listing from company documenting performance of survey done under direct supervision<br>4. Confirming letters from CME/CEU granting<br>5. Letters, certificates, or other documents from manufacturers’ or other formal training courses<br>6. Modality specific CME/CEU certificates | 2. CME/CEU certificates plus agenda, course outline, or syllabus<br>3. Confirming letters from CME/CEU granting<br>4. Letters, certificates, or other documents from manufacturers’ or other formal training courses<br>5. Modality specific CME/CEU certificates

| **Continuing Experience**<br>(2 facilities-6 units/24 months-final regs) | 1. Copy or coversheet of survey<br>2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done<br>3. Letter from facility or listing from company documenting performance of survey done under direct supervision<br>4. Confirming letters from CME/CEU granting<br>5. Letters, certificates, or other documents from manufacturers’ or other formal training courses<br>6. Modality specific CME/CEU certificates | 2. CME/CEU certificates plus agenda, course outline, or syllabus<br>3. Confirming letters from CME/CEU granting<br>4. Letters, certificates, or other documents from manufacturers’ or other formal training courses<br>5. Modality specific CME/CEU certificates

| **Continuing Education** (15 CME/36 months) | 1. CME/CEU certificates<br>2. Confirming letters from CME/CEU granting<br>3. Letters, certificates, or other documents from manufacturers’ or other | 1. CME/CEU certificates<br>2. Confirming letters from CME/CEU granting<br>3. Letters, certificates, or other documents from manufacturers’ or other

http://www.fda.gov/cdrh/dmqrp/6400.html
<table>
<thead>
<tr>
<th></th>
<th>formal training courses</th>
<th>formal training courses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing Mammographic Modality Specific Education-final regs</td>
<td>N/A</td>
<td>1. Mammography modality specific CME/CEU certificates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. CME/CEU certificates (plus agenda, course outline, or syllabus)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Confirming letters from CME/CEU granting organizations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
</tr>
<tr>
<td>Requalification-Experience-final regs-done under direct supervision</td>
<td>1. Copy or coversheet of survey done under direct</td>
<td>1. CME/CEU certificates</td>
</tr>
<tr>
<td></td>
<td>2. Letter from facility or listing from company providing the physics</td>
<td>2. Confirming letters from CME/CEU granting</td>
</tr>
<tr>
<td></td>
<td>performance of survey done under direct</td>
<td>3. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
</tr>
<tr>
<td>Requalification-Education</td>
<td>1. CME/CEU certificates</td>
<td>1. CME/CEU certificates</td>
</tr>
<tr>
<td></td>
<td>2. Confirming letters from CME/CEU granting</td>
<td>2. Confirming letters from CME/CEU granting</td>
</tr>
<tr>
<td></td>
<td>3. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
<td>3. Letters, certificates, or other documents from manufacturers’ or other formal training courses</td>
</tr>
</tbody>
</table>

Uploaded on May 19, 1999